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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,814	07/28/2006	Mark J Papania	6395-68278-03	5324

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EXAMINER

SKORUPA, VALERIE LYNN

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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11/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,814	Applicant(s) PAPANIA ET AL.	
	Examiner VALERIE SKORUPA	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-25 and 59-63 is/are allowed.
- 6) ☒ Claim(s) 26-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This office action is responsive to the amendment filed on August 26, 2010. As directed by the amendment: claims 1, 24, 26, 30, 42, and 56-58 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-63 are presently pending in the application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 42-48, 51, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Papania et al. (WO 02/074372).

3. As to claim 42, Papania discloses a handheld aerosolizing device (Fig. 1-3) comprising an aerosolizing element 90 comprising a front portion 138 having an opening extending completely therethrough (see Fig. 5C), a rear portion 124 having an opening extending completely therethrough (see Fig. 5C), a chamber 112 defined between the front and rear portion, an orifice plate 106 aligned with the opening 138 in the front portion, and a flexible diaphragm 110 aligned with the opening in the rear portion 124 opposite the orifice plate 106; an actuator 126, 128 coupled to the flexible diaphragm 110 through the opening of the rear portion 124 of the aerosolizing element to exert vibratory oscillations on the flexible diaphragm of the disposable aerosolizing

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element to aerosolize agent in the element (pg. 18, ln. 8-13); wherein aerosolized agent is expelled through orifices in the orifice plate and the opening in the front portion of the aerosolizing element; and wherein the aerosolizing element prevents the agent from contacting the actuator (see Fig. 5C).

4. As to claim 43 and 44, Papania discloses a fluid passageway 112 (Fig. 6) from a source of agent 24 (Fig. 3) to the patient interface 54 is substantially contained within the aerosolizing element 90 and the element 90 is separately removable from the device (see Fig. 6)

5. As to claim 45-48, Papania discloses that the aerosolizing element is shaped for direct connection to the source of agent 24 (see Fig. 3), that the aerosolizing element is pre-filled with a volume of agent and the volume is sufficient for multiple single doses (see Fig. 6).

6. As to claim 51, Papania discloses a nasal prong 54 (Fig. 3, pg. 14, ln. 18-24).

7. As to claim 56, Papania discloses a hand-held housing 8 containing the aerosolizing element 90 and the actuator (see Fig. 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 26-34, 37, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al., in view of Giachino et al. (US Patent No. 4,647,013).

10. As to claim 26, Papania discloses an aerosolizing device (Fig. 1-3) comprising: a housing 8 sized and shaped to be held in the hand of a user, a disposable aerosolizing element 90 (the aerosolizing element 90 is capable of being disposed by the user) disposed in the housing 8 and capable of expelling aerosolized agent, the aerosolizing element comprising a chamber, agent releasing orifices, a movable element opposite the agent releasing orifices; an oscillator (pg. 9, ln. 19) disposed in the housing and positioned to exert vibratory oscillations on the movable element, and a patient interface 54 coupled to the housing 8, but does not disclose projections disposed in the chamber and configured so maintain a minimum spacing between the movable element and the orifices or that the aerosolizing element is removable from the housing. However, Fig. 6 shows the element being a separate component from the rest of the device and it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the element removable in order to allow cleaning or replacing of parts, for example. Furthermore, Giachino discloses projections (while Fig. 15 shows only one projection 153, Fig. 10 shows multiple projections 101 can be used in place of one projection when multiple orifices 72 are present, col. 3, ln. 38-43) within a chamber of an aerosolizing element 130 (Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the aerosolizing element of Papania to include projections which contact opposing surfaces of the

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chamber as taught by Giachino in order to prevent fluid from leaking through the orifices when the device is not activated.

11. As to claim 27, Papania discloses a compressed air source 92 (Fig. 6, pg. 16, ln. 18-20).

12. As to claim 28, Papania discloses that some of the air conveyed by the compressed air source is directed to cool the oscillator (Fig. 6 shows the air path from source 92 through holes 146 and out through the top of the element 90. Therefore, it appears that the air would be directed past the oscillator to cool the oscillator).

13. As to claim 29, Papania discloses air inlet holes positioned to allow entry of atmospheric air into the device (pg. 17, ln. 29-30).

14. As to claim 30, Papania discloses that the aerosolizing element has a flexible portion 110 at least partially defining the chamber 112 (Fig. 6), wherein the flexible portion 110 that can be manually squeezed by a user (pg. 12, ln. 21-27).

15. As to claim 31, Papania discloses an inlet 38 (Fig. 6).

16. As to claim 32, Papania discloses a body-mountable pack (Fig. 8B) and a power source providing an electrical connection from one or more batteries to the actuator, wherein the batteries are disposed in the pack (pg. 5, ln. 29-30).

17. As to claim 33, Papania discloses an air pump (pg. 16, ln. 18-24) and an air conduit 92 fluidly connecting the air pump to the housing 8

18. As to claim 34, Papania discloses that the pack is worn around the user's waist or on the user's shoulder (backpack frame 158, Fig. 8B, pg. 18, ln. 29)

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19. As to claim 37, Papania discloses that the patient interface comprises a one-way valve 50 (Fig. 3pg. 14, ln. 27-30).

20. As to claim 58, Papania discloses a method of using an aerosolizing device comprising administering an aerosolized agent from the aerosolizing device (Fig. 1-3) by applying vibratory oscillations to a disposable aerosolizing element 90 in the aerosolizing device (pg. 18, ln. 3-20), but does not disclose disposing of the element after administering the agent, or that the aerosolizing element comprises projections disposed in the chamber configured to maintain a minimum spacing between the movable element and the orifices. However, it is a well known practice to dispose of a product once a user is finished using it. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Papania to include disposing of the element in order to replace the device with a newer one, for example. Furthermore, Giachino discloses projections (while Fig. 15 shows only one projection 153, Fig. 10 shows multiple projections 101 can be used in place of one projection when multiple orifices 72 are present, col. 3, ln. 38-43) within a chamber of an aerosolizing element 130 (Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the aerosolizing element of Papania to include projections which contact opposing surfaces of the chamber as taught by Giachino in order to prevent fluid from leaking through the orifices when the device is not activated.

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21. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al., in view of Giachino, as applied to claim 26 above, and further in view of Monson (US Patent No. 6,612,049).

22. The modified device of Papania discloses that the patient interface is intended for disposal after use (pg. 14, ln. 23-24), but does not disclose that the patient interface is a mask that is porous to air. However, Monson discloses a porous mask 1 attached to an administering device (Fig. 1, col. 1, ln. 49-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Papania to include the porous mask as taught by Monson in order to provide a suitable means for administering agent to the nose and mouth of the patient while still allowing the patient to breath through the mask.

23. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al. in view of Giachino, as applied to claims 26 and 37 above, and further in view of Gallem et al (US Patent Publication 2003/0205226).

24. The modified device of Papania discloses the claimed invention except that the one way valve is a duckbill valve. However, Gallem teaches a one-way valve 152 (Fig. 5A-5B) that is a duckbill valve (paragraph [0019], ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the valve of Papania to be a duck-bill valve as taught by Gallem in order to provide a suitable alternative type of valve to prevent exhalation air from entering the device through the mouthpiece.

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25. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al. in view of Giachino, as applied to claim 26 above, and further in view of Egilmex (US Patent No. 4,945,929).

26. The modified device of Papania discloses the claimed invention except that the interface comprises one or more baffles. However, Egilmex teaches baffles in a patient interface of an aerosolizing device (col. 1, ln. 54-col. 2, ln. 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Papania to include the baffles as taught by Egilmex in order to create turbulent mixing of the aerosol.

27. Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al., in view of Giachino, as applied to claim 26 above, and further in view of Hess et al. (US Patent No. 6,196,219).

28. The modified device of Papania discloses the claimed invention except for an aerosolization rate monitor. However, Hess discloses an aerosolization rate monitor 19 (col. 10, ln. 31-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Papania to include the aerosolization rate monitor as taught by Hess in order to provide a means for effectively measuring and controlling drug flow.

29. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania, in view of Giachino, as applied to claim 26 above, and further in view of Bruna et al. (US Patent No. 5,447,151).

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30. The modified device of Papania discloses the claimed invention except for a counting device. However, Bruna teaches a counting device used in an aerosolizing device (col. 12, ln. 43-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hess ('219) to include the counting device as taught by Bruna in order to provide information to the user of how much agent has been dispensed or is left.

31. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al., and further in view of Monson (US Patent No. 6,612,049).

32. Papania discloses that the patient interface is intended for disposal after use (pg. 14, ln. 23-24), but does not disclose that the patient interface is a mask that is porous to air. However, Monson discloses a porous mask 1 attached to an administering device (Fig. 1, col. 1, ln. 49-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Papania to include the porous mask as taught by Monson in order to provide a suitable means for administering agent to the nose and mouth of the patient while still allowing the patient to breath through the mask.

33. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al., in view of Hess et al. (US Patent No. 6,196,219).

34. The modified device of Papania discloses the claimed invention except for an aerosolization rate monitor. However, Hess discloses an aerosolization rate monitor 19 (col. 10, ln. 31-36). Therefore, it would have been obvious to one of ordinary skill in the

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art at the time the invention was made to modify the device of Papania to include the aerosolization rate monitor as taught by Hess in order to provide a means for effectively measuring and controlling drug flow.

35. Claims 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papania, in view of Hess et al., as applied to claims 26 and 52 above, and further in view of Everhart (US Patent No. 5,186,057).

36. The modified device of Papania discloses the claimed invention, as described in claims 22-23, except that the aerosolization rate monitor comprises a light source, a light detector, a controller, a visual indicator, and first and second opposing reflective surfaces on the aerosolizing element. However, Everhart teaches a flow rate monitor comprising a light source, a light detector, a controller, first and second reflective surfaces (col. 3, ln. 61-col. 4, ln. 10), and a visual indicator (col. 8, ln. 68). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the aerosolization monitor of the modified Papania device to include the light source, detector, controller, first and second reflective surfaces and visual indicator as taught by Everhart in order to provide a suitable means for measuring the rate of flow of the agent and provide useful information to the user.

37. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Papania et al.

38. Papania discloses a component in which at least batteries are positioned, the component having a power connection to the housing providing an electrical connection

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from the batteries to the actuator, the component adapted to be carried by the user (the entire device is handheld), but does not disclose that the component is separate from the housing. However, choosing to make the component housing the batteries separate from the device's housing is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Papania's component to be separable from the housing in order to allow for replacement of parts, for example when the batteries need to be replaced.

Allowable Subject Matter

39. Claims 1-25 and 59-63 are allowed.

Response to Arguments

40. Applicant's arguments filed August 26, 2010 have been fully considered but they are not persuasive. Applicant argues on page 15 of the remarks that a modification of Papania to include the projections of Giachino is improper because the orifices of Papania need to remain open in order to release the agent. However, the argument is not well taken because the flexible diaphragm of Papania could function to release the agent when the actuator pulls the diaphragm away from the orifice plate, thus separating the projections from the orifices as Giachino's device works. With this modification, Papania's device would still release agent upon activation of the actuator and have the added benefit of closing the orifices when the device is not activated in order to prevent leakage of the agent when the device is not in use.

Conclusion

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41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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